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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,500	06/04/2001	John E. Ware	QMET-201	5112
24972	7590	10/18/2005	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			BLECK, CAROLYN M	
			ART UNIT	PAPER NUMBER
			3626	
DATE MAILED: 10/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,500

Applicant(s)

WARE ET AL.

Examiner

Carolyn M. Bleck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/7/02 and 1/30/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 4 June 2001. Claims 1-40 are pending. This application claims the benefit of priority to provisional application 60/209105. The IDS statements filed 30 January 2003 and 7 February 2002 have been entered and considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 9-11, 13-24, 26-28, and 31-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999).

(A) As per claim 1, Ware discloses a method for making a dynamic healthcare assessment comprising:

(a) selecting questions for a customized questionnaire or test pertaining to a patient's health status, wherein the health status pertains to health conditions such as

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mental health issues or headaches, wherein the test has multiple questions (pg. 11, col. 2-3, pg. 12 col. 1-3);

(b) administering said questionnaire or test to a patient by providing one question at a time to said patient (pg. 12, col. 1); and

(c) after each question, evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score and dynamically modifying said test if said estimated confidence level is outside a pre-determined threshold (pg. 11 col. 3 par. 2, pg. 12 col. 1-2, pg. 13 col. 1-2).

(B) As per claim 2, Ware discloses generating a report for a physician and patient, wherein the report can be used to develop an effective treatment plan and then monitor how much the patient is helped (pg. 12 col. 3 par. 2).

(C) As per claim 3, Ware discloses the questionnaire pertaining to mental health assessments or headache sufferers, wherein the questions focus on the severity of a patient's headache and disability as well as how the headache's affect individual patient's in terms of their work productivity, social function, and family relationships (pg. 12 col. 3 par. 1-2).

(D) As per claims 4-5, Ware discloses ranking the plurality of questions in accordance with said estimated score and selecting a question based on the ranking, where the

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question has not been administered to the patient and the selecting a question includes selecting the highest ranked question (see pg. 12 col. 1). Note Ware's discussion of beginning with an initial score estimate, then selecting and presenting the optimal scale item based on the initial score estimate, then scoring the optimal scale item and re-estimating the health score and confidence interval.

(E) As per claim 6, Ware discloses terminating said administration of said test if it is determined that said estimated confidence level is within said threshold (pg. 12 col. 1 par. 2-3).

(F) As per claim 7, Ware discloses the threshold varying as a function of the estimated score (pg. 12 col. 1-2).

(G) As per claim 9, Ware discloses choosing an answer to a question on the bipolar general mental health of a patient, where the answers range from emotional distress to well being, including extremely bothered and not at all bothered (pg. 13 col. 1-2) (it is noted the answers cited by Ware are considered to be a form of a "list of possible answers").

(H) As per claims 10-11, Ware discloses estimating each person's score and confidence level based on their answers including analyzing the answers for systematic errors and quality (pg. 13 col. 1-2).

(I) As per claim 13, Ware discloses comparing said answers provided by said patient with answers provided by other patients in said mental health questionnaires (pg. 12 col. 1-2 comparing scores to 2,753 patients who participated in the study, pg. 13 col. 1-2).

(J) As per claims 14-16, Ware discloses administering the dynamic assessment over a web browser and Internet or telephone (pg. 12 col. 3 par. 1-2).

(K) As per claim 15, Ware discloses the report being received over the Internet or telephone (pg. 12 col. 3 par. 1-2).

(L) As per claim 17, Ware discloses the questionnaire or test pertaining to severity of headaches (pg. 12 col. 3 par. 1), general overall health (pg. 12 col. 3 par. 1), effectiveness of treatment, self-perceived status (pg. 12, col. 1-3 see mental health and headaches discussion, pg. 13 col. 1-2 see mental health discussion).

(M) System claims 18-24, 26-28, and 31-34 repeat the subject matter of method claims 1-7, 9-11, and 14-17, respectively, as a set of apparatus elements rather than as a series of steps. As the underlying processes of claims 1-7, 9-11, and 14-17 have been shown to be fully disclosed by the teachings of Ware in the above rejections of claims 1-7, 9-11, and 14-17, it is readily apparent that the system disclosed collectively by Ware

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includes the apparatus to perform these functions. Note, the discussion in Ware of a computerized adaptive test and software designed to implement the method discussed in claim 1 (pg. 11 col. 2-3). As such, these limitations are rejected for the same reasons given above for method claims 1-7, 9-11, and 14-17, and incorporated herein.

(N) Claims 35-40 repeat method and system claims 1, 6, 17, and 18, and are therefore rejected for the same reasons as those claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8, 12, 25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999).

(A) As per claims 8 and 25, Ware discloses the method using "computerized adaptive tests." The Examiner respectfully submits that computerized adaptive tests are old and well known in the art as discussed by Ware (pg. 11 col. 2 par. 2). The Examiner respectfully submits that using a database of questions and answers pertaining to the

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area being tested is also old and well known in the art of computerized adaptive tests.

The motivation for including this feature of database in Ware's method being to select questions tailored to the test-taker from a large pool of questions (pg. 11 col. 2 par. 2).

(B) As per claim 12 and 29, Ware discloses beginning with an initial score estimate, then selecting and presenting the optimal scale item based on the initial score estimate, then scoring the optimal scale item and re-estimating the health score and confidence interval (see pg. 12 col. 1). As per the recitation of statistically analyzing said answers provided by said patient for estimating non-responsive answers to said test, the Examiner respectfully submits that it is well known in the art of computerized adaptive tests to analyze answers that are non-responsive. For example, Ware discloses analyzing the score to a question by a patient, and it is well known in the art to include analyzing any answer that was not completed by the patient. The motivation being to score questions dynamically to produce a better score of a patient's health status (Ware; pg. 11 col. 3 par. 2).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches system and method for computer based testing (5,565,316), computer implemented medical integrated decision support system (6,697,783), system for monitoring and managing the health care of a patient population (6,385,589), system and method for determining a

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reference baseline of individual patient status for use in an automated collection and analysis patient care system (6,280,380), system for and method of collecting and populating a database with physician/patient data for processing to improve practice quality and healthcare delivery (6,151,581), system and process for information management and reporting (5,262,943), and system for collecting medical data (5,006,699).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (571) 272-6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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8. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(571) 273-8300 [Official communications]

(571) 273-8300 [After Final communications labeled "Box AF"]


(571) 273-6767 [Informal/ Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.

CB

CB

October 6, 2005


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
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